

September 30, 1999

from the desk of Anne Miller
President/CEO 8533 88 OCT 5 A10 :30

Dockets Management Branch (HFA-305),
Food & Drug Administration, 5630 Fishers Lane, Room 106 1,
Rockville, MD, 20852

Dear Sir/Madam,

REF: 98N-1215

In response to your proposed ruling for foreign establishments to identify a US agent along with our registration 5 10K complying with the your department of FDA, please consider my comments as follows:

1. Our company has been registered with FDA since 1988 with very limited sales to-date in the US.
2. Cool Eyes is a personal protective product - eye protection for sun tanning. Since our initial registration with your department we have kept the rules as to the directions we were given representing our product in the marketplace in your country.
3. As an example, our sales were approximately \$1500.00 to the US a year. An agent's cost would adversely affect our export business to your country. We would not be able to afford this extra compliance cost of doing business in the USA.
4. To-date we have not established a real market and would very much like an opportunity to do so.
5. Our ability to continue marketing our product in your country would be stopped at your borders with 'this additional financial burden of this proposal imposed on our small company which currently has such limited sales. .

We would appreciate cancellation of this considered proposal, or at least an extension of time to see if we can establish a viable market in the U.S., so we as GOOD NEIGHBOURS to the North would like the SPECIAL QUALITY OF RELATIONSHIP we have enjoyed till now and continue working together into the next millenium as a GREAT TEAM CANADA and the UNITED STATES OF AMERICA.

Your favorable consideration on my comments and views regarding this proposal will be much appreciated.

Sincerely,


Anne Miller

98N-1215

www.cooleyes.com

Toll Free: 1-888-689-2168

e-mail: info@cooleyes.com

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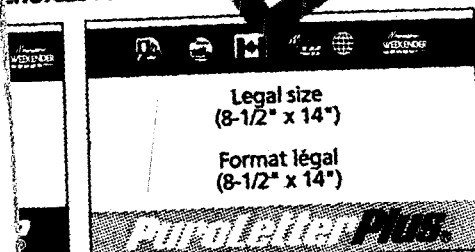
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Rockville MD 20852
Dr. K. M. Hall (HFA 305)
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